

## § 32.15

or distribution such products containing byproduct material for use pursuant to §30.15 of this chapter will be approved if:

(a) The applicant satisfies the general requirements specified in §30.33 of this chapter;

(b) The applicant submits sufficient information regarding the product pertinent to evaluation of the potential radiation exposure, including:

(1) Chemical and physical form and maximum quantity of byproduct material in each product;

(2) Details of construction and design of each product;

(3) The method of containment or binding of the byproduct material in the product;

(4) Procedures for and results of prototype testing to demonstrate that the material will not become detached from the product and that the byproduct material will not be released to the environment under the most severe conditions likely to be encountered in normal use of the product;

(5) Quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet;

(6) The proposed method of labeling or marking each unit, except timepieces or hands or dials containing tritium or promethium-147, and its container with the identification of the manufacturer or initial transferor of the product and the byproduct material in the product;

(7) For products for which limits on levels of radiation are specified in §30.15 of this chapter, the radiation level and the method of measurement;

(8) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the product.

(c) Each product will contain no more than the quantity of byproduct material specified for that product in §30.15 of this chapter. The levels of radiation from each product containing byproduct material will not exceed the limits specified for that product in §30.15 of this chapter.

(d) The Commission determines that:

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(1) The byproduct material is properly contained in the product under the most severe conditions that are likely to be encountered in normal use and handling.

(2) For automobile lock illuminators, the product has been subjected to and meets the requirements of the prototype tests prescribed by §32.40, schedule A.

[31 FR 5316, Apr. 2, 1966, as amended at 34 FR 6652, Apr. 18, 1969; 43 FR 6922, Feb. 17, 1978; 63 FR 32971, June 17, 1998]

### § 32.15 Same: Quality assurance, prohibition of transfer, and labeling.

(a) Each person licensed under §32.14 shall:

(1) Maintain quality assurance practices in the manufacture of the part or product, or the installation of the part into the product;

(2) Subject inspection lots to such testing as may be required as a condition of the license issued under §32.14 taking a random sample of the size required by the tables in §32.110, and for Lot Tolerance Percent Defective of 5.0 percent, accept or reject inspection lots in accordance with the directions of §32.110; and

(3) Visually inspect each unit, except electron tubes containing byproduct material, in inspection lots. Any unit which has an observable physical defect that could affect containment of the byproduct material shall be considered as a defective unit.

(b) An application for a license or for amendment of a license may include a description of procedures proposed as alternatives to those prescribed by paragraph (a)(2) of this section, and proposed criteria for acceptance under those procedures. The Commission will approve the proposed alternative procedures if the applicant demonstrates that the operating characteristic curve or confidence interval estimate for the alternative procedures provides a Lot Tolerance Percent Defective of 5.0 percent at the consumer's risk of 0.10.

(c) No person licensed under §32.14 shall transfer to other persons for use under §30.15 of this chapter or equivalent regulations of an Agreement State:

(1) Any part or product which has been tested and found defective under

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the criteria and procedures specified in the license issued under § 32.14, unless the defective units have been repaired or reworked and have then met such criteria as may be required as a condition of the license issued under § 32.14; or

(2) Any inspection lot which has been rejected as a result of the procedures in § 32.110 or alternative procedures in paragraph (b) of this section, unless the defective units have been sorted and removed or have been repaired or reworked and have then met such criteria as may be required as a condition of the license issued under § 32.14.

(d) Label or mark each unit, except timepieces or hands or dials containing tritium or promethium-147, and its container so that the manufacturer or initial transferor of the product and the byproduct material in the product can be identified.

[31 FR 5317, Apr. 2, 1966, as amended at 34 FR 6652, Apr. 18, 1969; 39 FR 22129, June 20, 1974; 43 FR 6922, Feb. 17, 1978]

### **§ 32.16 Certain items containing by-product material: Records and reports of transfer.**

(a) Each person licensed under § 32.14 or § 32.17 shall maintain records of all transfers of nuclear material and file a report with the Director of Nuclear Material Safety and Safeguards by an appropriate method listed in § 30.6(a) of this chapter, with a copy to the appropriate NRC Regional Office listed in appendix D to part 20 of this chapter.

(b) The report must include the following information on items transferred to other persons for use under § 30.15 or § 30.16 of this chapter or equivalent regulations of an Agreement State:

(1) A description or identification of the type of each product;

(2) For each radionuclide in each type of product, the total quantity of the radionuclide; and

(3) The number of units of each type of product transferred during the reporting period.

(c) The licensee shall file the report within 30 days after:

(1) Five years after filing the preceding report; or

(2) Filing an application for renewal of the license under § 30.37; or

(3) Notifying the Commission under § 30.34(f) of the licensee's decision to permanently discontinue activities authorized under the license issued under § 32.14 or § 32.17.

(d) The report must cover the period between the filing of the preceding report and the occurrence specified in paragraphs (c) (1), (2), or (3) of this section. If no transfers of byproduct material have been made under § 32.14 or § 32.17 during the reporting period, the report must so indicate.

(e) The licensee shall maintain the record of a transfer for a period of one year after the event is included in a report to the Commission.

[48 FR 12333, Mar. 24, 1983; 48 FR 23383, May 25, 1983, as amended at 68 FR 58804, Oct. 10, 2003]

### **§ 32.17 Resins containing scandium-46 and designed for sand-consolidation in oil wells: Requirements for license to manufacture, or initially transfer for sale or distribution.**

An application for a specific license to manufacture, or initially transfer for sale or distribution, synthetic plastic resins containing scandium-46 for use pursuant to § 30.16 of this chapter will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter;

(b) The product is designed to be used only for sand-consolidation in oil wells;

(c) The applicant submits the following information:

(1) The general description of the product to be manufactured or initially transferred.

(2) A description of control procedures to be used to assure that the concentration of scandium-46 in the final product at the time of distribution will not exceed  $1.4 \times 10^{-3}$  microcurie/milliliter.

(d) Each container of such product will bear a durable, legible label approved by the Commission, which contains the following information:

(1) The product name;

(2) A statement that the product contains radioactive scandium and is designed and manufactured only for sand-consolidation in oil wells;

(3) Instructions necessary for proper use; and